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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,594	12/12/2006	Elisabeth Arkenau-Maric	107101-47	2497

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Briscoe, Kurt G.
Norris McLaughlin & Marcus, PA
875 Third Avenue, 8th Floor
New York, NY 10022

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/567,594	ARKENAU-MARIC ET AL.
	Examiner	Art Unit
	HASAN AHMED	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *20 and 28-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *see continuation sheet*.	6) ☐ Other: _____.

6 February 2006, 13 September 2006, 27 August 2007, 25 November 2008, 12 March 2010, 3 June 2010, 22 October 2010, 21 January 2011, 2 March 2011, 11 April 2011, and 4 May 2011

DETAILED ACTION

Receipt is acknowledged of applicants information disclosure statements filed on 6 February 2006, 13 September 2006, 27 August 2007, 25 November 2008, 12 March 2010, 3 June 2010, 22 October 2010, 21 January 2011, 2 March 2011, 11 April 2011, and 4 May 2011.

* * * * *

Election/Restrictions

Applicants' election with traverse of Group I and claim 19 in the reply filed on 28 April 2011 is acknowledged. The traversal is on the ground(s) that searching all of the claims would not entail a serious search burden. This is not found persuasive because each group requires a distinct field of search not required by the other group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20 and 28-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and group, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in the reply filed on 28 April 2011.

* * * * *

Status of Claims

Claims 1-19 and 21-27 are rejected. Claims 20 and 28-36 are withdrawn. No claims are cancelled. No claims are allowed.

* * * * *

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Based on the priority documents filed, the earliest possible effective filing date is 6 August 2003, based on GERMANY 103 36 400.5.

* * * * *

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 6 February 2006, 13 September 2006, 27 August 2007, 25 November 2008, 12 March 2010, 3 June 2010, 22 October 2010, 21 January 2011, 2 March 2011, 11 April 2011, and 4 May 2011 were filed before the mailing date of the first action on the merits. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim contains several trademark/trade names. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or

product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the polymers for the capsule and accordingly, the identification/description is indefinite.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-14, 17-19, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2003/0068392 (“Sackler”), further in view of U.S. Patent No. 6,592,901 ("Durig"), as evidenced by U.S. 2010/0015223 (“Cailly-Dufestel”).

Sackler teaches an oral dosage form comprising an opioid analgesic, an opioid antagonist, and an irritant (see, e.g., abstract), suggesting claims 1, 11, and 12. The dosage form may comprise a tablet (see [0100]), suggesting claim 2. The dosage form may be particulate (see, e.g., [0085]), suggesting claim 3. The disclosed composition may further comprise polyethylene oxide having an average molecular weight of, e.g., 7

million (see [0174]), suggesting claims 4-7. The formulation may further comprise a wax, such as beeswax (see paragraph 0122), reading on claims 8 and 9. Regarding claim 13, Sackler states that the irritant provides a burning or irritating effect to the abuser upon inhalation, injection, and/or swallowing the tampered dosage form (see [0023]). The disclosed aversive agent may comprise capsaicin (see [0051] and [0052]), suggesting claims 14 and 17. Regarding claim 18, Sackler teaches, e.g., polyacrylic acids such as CARBOPOL™ (see [0053]). Regarding claim 19, the reference teaches opioid antagonists such as naloxone and naltrexone (see [0058] – [0063]). Regarding claim 23, Sackler teaches peppermint oil (see [0048]). The bitter property of peppermint oil is an inherent characteristic of the composition. Regarding claim 24, Sackler teaches that aversive agent particles may be coated with a hydrophobic coating (see [0088]). Such particles would be spatially separated from the active ingredient, would be present in a separate subunit, and would not exert their effect in the body and/or on taking. Additionally, Sackler teaches that the aversive agent may be separate from the matrix containing the active ingredient (see [0104]). Regarding claims 25 and 26, Sackler teaches a controlled release dosage form which may include a controlled release material which is incorporated into a matrix along with the opioid analgesic (see [0104]). Regarding claim 27, the matrix may be comprised of materials such as waxes and polymers (see [0120]).

Sackler explains that the aversive agent discourages an abuser from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage from (see, e.g., [0023]).

The references are silent with respect to breaking strength, however, tablets with very high hardness or crushing strength (breaking strength) were known in the art at the time the instant application was filed. Durig teaches a pharmaceutical composition that uses a form of ethylcellulose that provides high compressibility and compactibility and provides excellent flow characteristics with low dusting and superior mechanical strength (see col. 3, lines 42-48).

Durig explains that, "...superior mechanical strength is a key parameter assuring longer release duration. Furthermore increased mechanical strength is a desirable attribute in compressed dosage forms as this assures their physical and dimensional stability and robustness during bulk handling operations such as tablet coating, conveying and filling into final containers and transportation." See paragraph bridging columns 4 and 5.

Medicaments which may be used with the composition disclosed by During include agents prone to abuse such as psychotropics, stimulants, analgesics, hypnotics, and sedatives (see col. 6, lines 25-41).

Disclosed crushing strength (reported in kilopond (kP) (see col. 10, lines 14-19)) was 10.2 to 18.8 kP (see Table 2). Cailly-Dufestel explains that 10 to 20 kP scaled down to the size of tablets is equivalent to about 1.4 to 2.8 MPa (see [0040]).

The processes disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the

product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an abuse-proofed, delayed release oral dosage form comprising an active agent, a polymer, a delayed-release matrix, an auxiliary substance, a wax, and a delayed-release coating, as taught by Sackler further in view of Durig as evidenced by Cailly-Dufestel. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it discourages an abuser from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage from, as explained by Sackler (see above). Additionally, the motivation for high breaking strength is increased release duration and physical and dimensional stability and robustness during bulk handling operations such as tablet coating, conveying and filling into final containers and transportation, as explained by Durig (see above).

*

2. Claims 1, 12, 15, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2003/0068392 ("Sackler"), in view of U.S. Patent No. 6,592,901 ("Durig"), as evidenced by U.S. 2010/0015223 ("Cailly-Dufestel"), further in view of U.S. 2003/0125347 ("Anderson").

Sackler, and Durig are discussed above.

While Sackler teaches the use of irritant substances such as capsaicin (see [0051] and [0052]), the reference does not teach the specific substances listed in claims 15 and 16. Additionally, Sackler does not teach an emetic such as those listed in claim 21.

Anderson teaches a pharmaceutical composition and an oral dosage form comprising an opiate and an irritant which is designed to discourage abuse of an opiate (see, e.g., abstract). The reference teaches irritants such as mustard and mustard derivatives (suggesting claims 15 and 16), as well as emetics such as ipecac (suggesting claim 21).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an abuse-proofed, delayed release oral dosage form comprising an active agent, a polymer, a delayed-release matrix, an auxiliary substance, an irritant such as mustard, an emetic such as ipecac, a wax, and a delayed-release coating, as taught by Sackler, in view of Durig as evidenced by Cailly-Dufestel, further in view of Anderson. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it discourages an abuser from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage from, as explained by Sackler (see above). Additionally, the motivation for high breaking strength is increased release duration and physical and dimensional stability and robustness during bulk handling

operations such as tablet coating, conveying and filling into final containers and transportation, as explained by Durig (see above).

*

3. Claims 1, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2003/0068392 (“Sackler”), in view of U.S. Patent No. 6,592,901 ("Durig"), as evidenced by U.S. 2010/0015223 (“Cailly-Dufestel”), further in view of U.S. 2005/0089475 (“Gruber”).

Sackler, and Durig are discussed above.

These references differ from the instant application in that they do not teach a dye as an aversive agent, However, use of a dye as an aversive agent in a composition designed to prevent abuse of opioid analgesics was known in the art at the time the instant application was filed, as evinced by Gruber (see, e.g., [0017]). Gruber explains that the dye is released when the dosage form is tampered with and provides a noticeable color which makes the act of abuse visible to the abuser and others such that the abuser is less likely to inhale, inject and/or swallow the tampered dosage form (see [0017]).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose an abuse-proofed, delayed release oral dosage form comprising an active agent, a polymer, a delayed-release matrix, an auxiliary substance, an aversive agent such a dye, a wax, and a delayed-release coating, as taught by Sackler in view of Durig as evidenced by Cailly-Dufestel, further in view of Gruber. One of ordinary skill in the art at the time the invention was made would have

been motivated to make such a composition because it discourages an abuser from tampering with the dosage form and thereafter inhaling, injecting, or swallowing the tampered dosage from, as explained by Sackler (see above). Additionally, the motivation for high breaking strength is increased release duration and physical and dimensional stability and robustness during bulk handling operations such as tablet coating, conveying and filling into final containers and transportation, as explained by Durig (see above).

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 and 21-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application Nos. 10/718,112; 10/890,707; 10/890,763; 11/348,295; 11/349,537; 11/349,544; 11/462,216; 12/140,470; and 12/140,665.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the each of the above-cited copending applications claim similar subject matter. For example, Application No. 10/890,763 recites an abuse-proofed oral dosage form with an active ingredient, synthetic or natural polymer, delayed release coating, and breaking strength of at least 500 N (*see* claim 1). Thus, the compositions recited in the claims of the copending applications listed above are directly within the scope of the compositions of the instant claims.

This is a genus-species situation, wherein the numerous species of the copending application claims are directly within the scope of the large genus of the pending claims, thereby creating an 'anticipation situation' in obvious type double patenting.

There are numerous applications that may necessitate a double patenting rejection due to the breadth of the claims, as can be seen by an inventors name search of US Patents and Applications. It would constitute an undue burden for the Examiner to specifically analyze each of the numerous patent applications. A quick search turned up the copending applications above that appear to have similar subject matter as claimed. The Examiner requests a complete list of both patents and pending applications, which may initiate a double patenting rejection because of the undue burden presented by the numerous overlapping subject matter with the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. A./
Examiner, Art Unit 1615

/S. TRAN/
Primary Examiner, Art Unit 1615